ATTACHMENTS

Attached hereto is a computer readable copy of the Sequence Listing, and a copy of the Sequence Listing printed on paper. The disk has been checked using the USPTO Checker Version 4.2 Program, and no errors were found.

VERIFICATION STATEMENT

I hereby state that the content of the paper copy of the Sequence Listing and the enclosed computer readable copy of the Sequence Listing are the same.

REMARKS

Applicant notes with appreciation the well-reasoned Office Action, Paper No. 20050423. This amendment is submitted in response thereto. By way of this amendment, non-elected claims 1-8 have been canceled. Independent claim 9 has been amended to recite the indication of a gram-positive infection. Support for this amendment is found in the instant specification at page 18, line 3. Additionally, new claims 15-28 have been added, support for which is found throughout the application and claims as filed and specifically including page 18, lines 13-20, and page 33, lines 9-13. As such, it is submitted that no new matter has been added to the application by way of this amendment.

A computer-readable disk and amendments to the specification have been provided in compliance with 37 CFR 1.821-1.825.

Currently, claims 9-14 stand rejected under 35 U.S.C. §112, first paragraph. Lastly, claims 9 and 10 stand rejected under 35 U.S.C. §102(b) as anticipated by Loyola-Rodriguez et al. (Journal of General Microbiology, 1992, Vol. 138, No. 2, pp. 269-274).

Remarks Directed to Rejection of Claims 9-14
Under 35 U.S.C. §112, First Paragraph

The basis of the rejection is that the specification has failed to teach or disclose the treatment of any or all infectious diseases with a composition provided according to the present invention.

Applicant submits that one skilled in the art upon a review of the written description of the invention would be able to practice the invention without undue experimentation for the reasons as detailed below. Applicant respectfully submits that by applying the factors as outlined in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), an analysis is lacking as to whether each and every recited step of the claimed invention was enabled. With a finding of enablement for each and every element of the claimed invention, there is longstanding case law that holds that the resulting invention is therefore enabled. Additionally, while Applicant believes that the *In re Wands* factors are satisfied by the instant specification, such a finding is not necessary to satisfy the enablement requirements of §112. The Federal Circuit stated in *Amgen* that "It is not necessary that a court review all the *Wands* factors to find a disclosure enabling." *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

Turning now to claim 9, the recited method step includes "administering to said subject an effective amount of a purified and isolated peptide having an amino acid sequence as set forth in SEQ ID No: 2, or a pharmaceutically acceptable salt, amide, ester or prodrug thereof." Applicant submits that the specification at page 12, line 5 – page 21, line 22 broadly teaches the compounding and administration by peptide according to SEQ ID No: 2.

In regard to the insufficiency of the instant specification to achieve a level of therapeutic success, Applicant submits that testing the susceptibility of a particular microorganism to an

inventive peptide is well within the talents of one of skill in the art. In support of this position, Applicant refers to the Loyola-Rodriguez reference for an exemplary teaching with respect to Table 2 of methodologies for measuring the level of success. Additionally, the efficacy of a given medical treatment has long been held to reside within the purview of the Food and Drug Administration and not within the Patent and Trademark Office.

In light of the above remarks, Applicant believes the claims as filed to be enabled. In effect, even though the pending application is lacking as to the effectiveness of claimed method with regard to the treatment of the infections detailed in the outstanding Office Action, namely *Moraxella catarrhalis*, *Plasmodium falciparum*, and HIV, Applicant submits that one of skill in the art certainly has the ability to test susceptibility of these pathogens towards an inventive composition without undue experimentation.

Nonetheless, Applicant has amended the pending claims commensurate with the spectrum of an inventive composition as detailed explicitly within the specification, namely gram-positive bacteria.

In light of the above remarks, reconsideration and withdrawal of the rejection as to pending claims 9-14 under 35 U.S.C. §112, first paragraph, is solicited.

Remarks Directed to Rejection of Claims 9 and 10 Under
35 U.S.C. §102(b) as Anticipated by Loyola-Rodriguez et al.

Anticipation has always been held to require absolute identity between the claimed invention and the teachings found within a single reference. Applicant submits that a reading of Loyola-Rodriguez makes clear that mutacin MT6223 is not anticipatory of peptide SEQ ID No: 2 found in claim 9.

Mutacin I according to the pending claims has a molecular weight of approximately 2364 Daltons, is made up of 24 amino acids in mature form (page 9, lines 6-8) and is highly thermostable (page 18, lines 6-7).

In contrast to mutacin I as the subject of the pending claims, mutacin MT6223 according to Loyola-Rodriguez is detailed on page 273, first full paragraph, as having a molecular mass of 6500 Daltons and the chemical structure of which is unknown and noted as being under current investigation. Additionally, mutacin MT6223 was grown on liquid culture in contrast to specification teaching provided at page 26, lines 3-16.

In light of marked difference in molecular weight and production conditions, Applicant submits that MT6223 per Loyola-Rodriguez is not mutacin I according to SEQ ID No: 2. Additionally, Loyola-Rodriguez lacks a structural characterization which is respectfully submitted to negate anticipation of the pending claims.

In light of the above remarks, reconsideration and withdrawal of the rejection of claims 9 and 10 under 35 U.S.C. §102(b) is solicited.

Summary

Claims 9-28 are the claims pending in this application. Claim 9 has been amended and new claims 15-28 have been added. All of the pending claims are submitted to be in allowable form and directed to patentable subject matter. Reconsideration and allowance of the claims is

solicited. Should the Examiner find to the contrary, she is respectfully requested to contact the undersigned attorney in charge of this application to resolve any remaining issues.

Respectfully submitted,

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DATE OF DEPOSIT July 28, 2005

I hereby certify that this paper or fee (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service "Express Mail Post Office To Addressee" Service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Janice R. Kuehn

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